K083628



# 510(k) Summary

MAY - 1 2009

According to the requirements of 21 CFR.807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**1. Submitter**

**Name,** All Medicus., Co. Ltd.
**Address,** #7608, Dong-il Techno Town 7th.,
823, Gwanyang 2-dong, Dongan-gu, Anyang.
**Contact** Gyeonggi-do, 431-062, Korea
Phone : (82) 31-425-8288
Fax : (82) 31-422-8589
Contact Person : Ms. Margaret Kim

**2. Date Prepared** Nov, 2008

**3. Device Name**

Propriety name : GlucoDr™ auto Blood Glucose Monitoring System
Common name : Blood glucose monitoring system
Classification name : Glucose Test System Class II
(21 CFR Section 862.1345, Product Code : LFR, NBW)
Quality control material Class I
(21 CFR Section 862.1660, Product Code : JJX)

**4. Predicate Device**

We claim substantial equivalence to the Roche Diagnostics Corporation, Accu-Chek Aviva System. (K043474)

**5. Device Description**

The GlucoDr™ auto blood glucose monitoring system consists of GlucoDr™ auto Test Meter, GlucoDr™ auto Test strips and GlucoDr™ auto control solution.

The GlucoDr™ auto blood glucose monitoring system is based on measurement of electrical currents caused by the reaction of glucose with reagents on the gold electrode strip. Glucose in the sample reacts with glucose dehydrogenase and mediators. This reaction creates electrical currents. The subsequent electrical currents are proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration by the algorithm programmed in the GlucoDr™ auto test meter.

**6. Intended use**

The GlucoDr™ auto blood glucose monitoring system is intended for in vitro diagnostic use (i.e., for external use only) for quantitative measurement of glucose in venous, arterial and capillary whole blood. Testing sites include traditional fingertip site along with palm, upper arm, forearm, thigh, and calf.

The GlucoDr™ auto blood glucose monitoring system may be used by healthcare professionals or for self testing by diabetic lay users in the mellitus at home as aid in monitoring the effectiveness of diabetes control program.

The GlucoDr™ auto blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates.

The GlucoDr™ auto control solution is for use with the The GlucoDr™ auto test meters and strips as a quality control check to verify the accuracy of blood glucose test results.

**7. Comparison to Predicate Device**

The GlucoDr™ auto blood glucose monitoring system has equivalent technological characteristics as the Accu-Chek Aviva System. The GlucoDr™ auto system also has the same intended use as the Accu-Chek Aviva System.

**8. Conclusion**

The GlucoDr™ auto blood glucose monitoring system is substantially equivalent to the predicate device system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 1 2009

All Medicus Co., Ltd.
c/o Ms. Margaret Kim
Regional Manager
No. 7608 Dong-il Techno Town 7TH
823 Gwanyang 2-dong, Dongan-gu
Anyang, Gyeonggi-do
Republic of Korea 431-062

Re: k083628
Trade/Device Name: GlucoDr™ auto Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR and JJX
Dated: April 28, 2009
Received: April 28, 2009

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): K083628

Device Name: **GlucoDr™ auto Blood Glucose Monitoring System**

Indication For Use:

The GlucoDr™ auto blood glucose monitoring system is intended for in vitro diagnostic use (i.e., for external use only) for quantitative measurement of glucose in venous, arterial and capillary whole blood. Testing sites include traditional fingertip site along with palm, upper arm, forearm, thigh, and calf.

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|---|---|---|
| Prescription Use ___√___<br>(21 CFR Part 801 Subpart D) | And/Or | Over the Counter Use ___√___<br>(21 CFR Part 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083628